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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,218	01/20/2004	Durward I. Faries JR.	1322.0057CNT	6438
27896	7590	11/10/2004	EXAMINER	
EDELL, SHAPIRO, FINNAN & LYTLE, LLC 1901 RESEARCH BOULEVARD SUITE 400 ROCKVILLE, MD 20850			JAGAN, MIRELLYS	
		ART UNIT	PAPER NUMBER	
			2859	

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/759,218	FARIES ET AL.
	Examiner	Art Unit
	Mirellys Jagan	2859

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 03 August 2004.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 47-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 47-68 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 January 2004 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Objections***

2. Claims 47-58 are objected to because of the following informalities:

Claim 47, "within said base" should be changed to --within said receptacle-- since the medical item rests on the base and not inside the base.

Claims 48-58 are objected to for being dependent on objected base claim 47. Appropriate correction is required.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,722,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 claims a medical device having all of the limitations of the broader claims 47-49.

5. Claims 50-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-4, 6-8, 5, 9, and 10, respectively, of U.S. Patent No. 6,722,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because base claim 1 claims a medical device having all of the limitations of the broader base claim 47.

6. Claims 59-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,722,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 claims a method having all of the limitations of the broader claims 59-61.

7. Claims 62-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-18, respectively, of U.S. Patent No.

6,722,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because base claim 12 claims a method having all of the limitations of the broader base claim 59.

8. Claims 59 and 68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,722,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 claims a medical device that visually indicates a temperature of a medical item having a particular temperature range for utilization placed therein, wherein the medical device includes a base and at least first and second panels attached to the base and a receptacle defined between the panels and the medical item is received within the receptacle defined between the panels; and the medical item has a temperature sensor assembly to directly measure the temperature of the medical item and provide a visual indication of the temperature, the temperature sensor assembly also including a voice synthesizer to provide an audio indication of the medical item temperature.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 47-49, 51, 52, 54, 59-61, 63, 64, and 66 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent 5,875,282 to Jordan et al [hereinafter Jordan].

Jordan discloses a medical device (10) for a medical item (16), the device comprising:

- a base and at least first and second panels attached to the base;
- a receptacle defined between the panels for receiving the medical item (16), wherein the medical item has a particular temperature range for utilization; and
- a temperature sensor assembly including a temperature sensing strip (80) disposed within the first panel to directly measure the temperature of the medical item (16) and provide a digital indication on a display (36) that visually indicates the measured item temperature;

wherein the receptacle is configured to enable the medical item to be in thermal relation with the temperature sensor; and the device is attached to a support structure (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Furthermore, in using the device disclosed above by Jordan, the method steps of claims 59-61, 63, 64, and 66 will naturally be followed.

#### *Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 47-49, 51, 52, 53, 59-61, 63, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,989,238 to Ginsburg in view of Jordan.

Referring to claims 47-49, 51, 52, 59-61, 63, and 64, Ginsburg discloses a medical device (10) for a medical item (30), the device comprising:

- a base and at least first and second panels attached to the base;
- a receptacle (28) defined between the panels for receiving the medical item (30), wherein the medical item has a particular temperature range for utilization;
- a temperature sensor assembly including a temperature sensor (34) disposed within the first panel (i.e., the bottom panel of the housing 12) to directly measure the temperature of the medical item; and
- visual means (24) for displaying a set point temperature for the medical device; wherein the receptacle is configured to enable the medical item to be in thermal relation with the temperature sensor (see figures 1 and 2; column 2, lines 25-35 and 45-53; column 3, lines 2-7, 18-22, and 26-31; and column 4, line 48-column 5, line 17).

Ginsburg does not disclose the assembly comprising means for visually indicating the measured temperature of the medical item by using a strip that provides a digital indication of the measured temperature.

Jordan discloses a medical device (10) for a medical item, the device comprising a housing defining a receptacle for receiving the medical item; and a temperature sensor assembly for directly measuring the temperature of the medical item, the assembly having means for visually indicating the measured temperature of the medical item by using a temperature sensing strip (80) that provides a digital temperature measurement indicated by a digital temperature

display. Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Referring to claims 47 and 59, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device of Ginsburg by replacing the temperature sensor assembly with an assembly as taught by Jordan, in order for the user to determine the actual temperature of the contents in the medical item before using the contents on a patient.

Furthermore, in using the device disclosed above by Ginsburg and Jordan, the method steps of claims 59-61, 63, and 64 will naturally be followed.

Referring to claims 47, 51-53, 59, and 63-65, Ginsburg discloses a portable medical device (10) for a medical item (30), the device comprising:

a base and at least first (i.e., the top panel of the housing 12) and second panels attached to the base;

a receptacle (28) defined between the panels for receiving the medical item (30), wherein the medical item has a particular temperature range for utilization;

a temperature sensor assembly to directly measure the temperature of the medical item; and

visual means (24) for displaying a set point temperature for the medical device;

wherein Ginsburg discloses that the device is portable (see figures 1 and 2; column 2, lines 25-35 and 45-53; column 3, lines 2-7, 18-22, and 26-31; column 4, lines 27-33; column 4, line 48-column 5, line 17; and column 5, lines 27-30).

Ginsburg does not disclose the assembly comprising means for visually indicating the measured temperature of the medical item by using a strip that provides a digital indication of the measured temperature; and a handle on the first panel.

Jordan discloses a medical device (10) for a medical item, the device comprising a housing defining a receptacle for receiving the medical item; and a temperature sensor assembly for directly measuring the temperature of the medical item, the assembly having means for visually indicating the measured temperature of the medical item by using a temperature sensing strip (80) that provides a digital temperature measurement indicated by a digital temperature display. Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Referring to claims 47 and 59, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device of Ginsburg by replacing the temperature sensor assembly with an assembly as taught by Jordan, in order for the user to determine the actual temperature of the contents in the medical item before using the contents on a patient.

Referring to claims 53 and 65, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device of Ginsburg and Jordan

by adding a handle on the first panel (i.e., the top panel of the housing 12), since Ginsburg discloses that the device is portable, and therefore a handle will facilitate transporting the device.

Furthermore, in using the device disclosed above by Ginsburg and Jordan, the method steps of claims 59 and 63-65 will naturally be followed.

13. Claims 47-49, 52, 54, 55, 58-61, 64, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,336,435 to Kashyap et al [hereinafter Kashyap] in view of Jordan.

Kashyap discloses a medical device (8) having a medical item (1) placed therein, the device comprising:

- a base and at least first and second panels attached to the base;
- a receptacle defined between the panels for the medical item therein, wherein the item has a particular temperature range for utilization; and

- a temperature sensor assembly (30) including a temperature sensor (31) disposed within the first panel to directly measure the temperature of the item;

- wherein the receptacle is configured to enable the medical item to be in thermal relation with the sensor; the device is attached to a support structure/thermal treatment system (4); and the temperature sensor may be an IR temperature sensor (see figures 2, 4, and 6; column 3, lines 10-16; and column 4, lines 10-36).

Kashyap does not disclose the assembly comprising means for visually indicating the measured temperature of the medical item.

Jordan discloses a medical device (10) for a medical item, the device comprising a housing defining a receptacle for receiving the medical item; and a temperature sensor assembly for directly measuring the temperature of the medical item, the assembly having means for visually indicating the measured temperature of the medical item by using a temperature sensing strip (80) that provides a digital temperature measurement indicated by a digital temperature display. Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature as it is heated (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Referring to claims 47 and 59, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the temperature sensor assembly of Kashyap by adding means for visually indicating the measured temperature of the medical item, as taught by Jordan, in order for the user to determine the actual temperature of the medical item when it is being heated.

Furthermore, in using the device disclosed above by Kashyap and Jordan, the method steps of claims 58-61, 64, 66, and 67 will naturally be followed.

14. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan in view of U.S. Patent 4,532,414 to Shah et al [hereinafter Shah].

Jordan discloses a device having all of the limitations of claim 56, as stated above in paragraph 10, except for the display being an LCD.

Shah discloses a device for a blood warming apparatus having temperature sensing means and a digital temperature display. Shah teaches that an LCD is useful for displaying a digital temperature measurement in the blood warming apparatus (see column 8, lines 51-68).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Jordan by using an LCD as the display since Shah teaches that LCDs are useful for displaying a digital temperature measurement in a blood warming apparatus.

15. Claims 57 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan in view of U.S. Patent 4,585,441 to Archibald.

Jordan discloses a device and method having all of the limitations of claims 57 and 58, as stated above in paragraph 10, except for the device including a voice synthesizer to provide an audio indication of the temperature.

Archibald discloses a device for IV fluid control having a voice synthesizer to provide an audible alarming signal. Archibald teaches that using a voice synthesizer is beneficial since it allows a positive indication of the alarming source from other alarming sources that may be present simultaneously with the device (see column 4, lines 30-38)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Jordan by adding a voice synthesizer to state the temperature, as taught by Archibald, in order to audibly discern the temperature measurements of the device from other medical devices.

Furthermore, in using the device disclosed above by Jordan and Archibald, the method steps of claim 68 will naturally be followed.

***Allowable Subject Matter***

16. Claim 50 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, amended to overcome the objections in this Office action, and upon the timely filing of a terminal disclaimer in compliance with 37 CFR 1.321(c).

17. Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and upon the timely filing of a terminal disclaimer in compliance with 37 CFR 1.321(c).

18. The following is a statement of reasons for the indication of allowable subject matter:  
The prior art of record does not disclose or suggest the following in combination with the remaining limitations of the claims:

A medical device for visually indicating a temperature of a medical item placed therein, the device comprising a temperature sensor assembly that includes a plurality of temperature sensitive substances each associated with a corresponding temperature range and responsive to a temperature of the medical item to provide a visual indication of the temperature of the medical item (see claim 50).

A method of visually indicating a temperature of a medical item placed in a medical device, the method comprising directly measuring a temperature of the medical item via a temperature sensor assembly that includes a plurality of temperature sensitive substances each associated with a corresponding temperature range and responsive to a temperature of the medical item to provide a visual indication of the temperature of the medical item (see claim 62).

***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents and publication disclose a medical device having temperature-sensing means:

U.S. Patent 6,123,827 to Wong et al  
U.S. Patent 4,735,609 to Comeau et al  
U.S. Patent 5,408,576 to Bishop  
U.S. Patent 6,566,631 to Faries, Jr. et al  
U.S. Patent 6,660,974 to Faries, Jr. et al  
U.S. Patent 6,768,085 to Faries, Jr. et al  
U.S. Patent 4,628,186 to Bergemann et al  
U.S. Patent 6,748,164 to Kuzyk  
U.S. Patent 5,125,069 to O'Boyle  
U.S. Patent 6,117,122 to Din et al  
U.S. Patent 4,314,143 to Bilstad et al  
U.S. Patent 4,808,159 to Wilson  
U.S. Patent Application Publication 2004/0170409 to Faries, Jr. et al

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mirells Jagan whose telephone number is 571-272-2247. The examiner can normally be reached on Monday-Friday from 11AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez can be reached on 571-272-2245. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJ  
November 8, 2004



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